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EXAMINER	
VU, JAKE MINH	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
02/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,634	SELA, YORAM	
	Examiner	Art Unit	
	Jake M. Vu	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-45* is/are pending in the application.

4a) Of the above claim(s) *44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/GB/08) Paper No(s)/Mail Date *9/29/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Restriction Requirement Response filed on 11/12/2009; Information Disclosure Statement filed on 09/29/2009; Request for Continued Examination and Amendment filed on 07/31/2009.

- Claim 29 has been amended.
- Claims 31-45 have been added.
- Claims 44-45 are withdrawn from further consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/31/2009 has been entered.

Election/Restrictions

Newly submitted claims 44 and 45 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original presented claims pertain to composition claims only, whereas claims 44 and 45 pertain to method claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 44 and 45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The use of the trademark EUDRAGIT® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The cellulose derivative does not meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus of derivatives of cellulose encompassed by the claim, since there is no description of the structural relationship of these derivatives provided in the specification and Applicant has not provided a description as to how the base molecule may be changed while remaining a derivative.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 32, 35, 38, 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 and 32 recite the limitation "GMS". It is unclear what GMS stands for, since no prior claim defines "GMS" and the specification does not define GMS.

Claim 30 recites the limitation "said additional polymeric" in claim 29. There is insufficient antecedent basis for this limitation in the claim.

Claims 32, 35, and 38 recites "comprises GMS or hydrophilic polymer layer", "comprises a binder", "comprises plasticizer". It is unclear if these claims "comprises" only these limitations or "further comprises" these limitations. For instance, claim 35 recites "venlafaxine hydrochloride layer comprises a binder", which can be interpret that the layer only has binder, but no venlafaxine hydrochloride. Or claim 38 recites "hydrophobic layer comprises a plasticizer" would interpret that plasticizer is the only limitation in the hydrophobic layer.

Note, venlafaxine is mistyped in claim 35.

Claim 41 contains the trade name Eudragit. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 16, and 19 rejected under 35 U.S.C. 102(b) as being anticipated by HEILIGENSTEIN (EP 0919236) **are withdrawn** in view of Applicant's amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over HEILGENSTEIN (EP 0919236) **are maintained** for reasons of record in the previous office action filed on 05/15/2008, 02/03/2009 and as discussed below.

Response to Arguments

Applicant argues that the pharmacological and/or clinical effects of the active pharmaceutical ingredient of the present invention (i.e. venlafaxine) and its similarity to the biological effects produced by duloxetine are of no relevance to the instantly claimed composition, a key aim of which is to enable controlled release of the highly soluble venlafaxine, and this would be well understood by those skilled in the art. It should be

emphasized in this regard that many pharmaceutically- active compounds assigned to the same class on the basis of their common biological activities (i.e. the effect of the drug on the patient's body) may differ considerably with respect to their pharmacokinetic properties (i.e. the effect of the patient's body on the drug). Thus, as discussed in Applicant's response dated April 5, 2007, venlafaxine is highly soluble in water as compared with most other anti-anxiety/SSRI compounds, namely, the compounds disclosed in Heiligenstein and especially duloxetine (the only demonstrated drug in Heiligenstein). In fact, duloxetine is nearly two hundred thousand-fold (!) less water soluble than venlafaxine (572 mg/ml; para. [0004] of instant application). Thus the stability problems (detailed in Applicant's former response) which are addressed and solved in Applicant's claims are not, indeed cannot be, addressed, disclosed or even hinted at in Heiligenstein. THE Examiner finds this argument unpersuasive, because HELIGENSTEIN specifically teaches using venlafaxine as the active drug (see claim 2; and pg. 4, 48). Thus, HEILIGENSTEN would inherently fix the stability problems that Applicant argued.

Applicant argues that Heiligenstein teaches only at best how to handle a slightly water soluble drug such as duloxetine, but provides no teaching on how to prepare an extended release composition comprising a highly soluble drug such as venlafaxine. Heiligenstein does not teach or suggest a composition comprising 30-60% w/w venlafaxine and 2-15% w/w hydrophobic polymer as in claim 31 or a method for preparing such a composition. Heiligenstein does not enable the person of ordinary skill in the art to reach Applicant's claimed composition because Heiligenstein only teaches

one how to achieve the Heiligenstein composition with a slightly water soluble drug, but does not teach the person of ordinary skill in the art how to achieve such a composition with a highly water soluble drug. The Examiner finds this argument unpersuasive, because HELIGENSTEIN specifically teaches using venlafaxine as the active drug (see claim 2; and pg. 4, 48). Thus, it would have been obvious to simply incorporate venlafaxine in place of duloxetine; and as discussed in the previous office action, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as the amount of drug release over a specific amount of time. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Applicant argues that the Examiner's argument that amounts of specific ingredients in a composition is a parameter that a person of ordinary skill in the art could routinely optimize with expected success, is not relevant in this case due to the different physical properties of Heiligenstein's demonstrated drug and the instantly claimed drug. Heiligenstein teaches using 8% w/w drug and 25.8% w/w hydrophobic polymer. Heiligenstein gives no direction as to the modifications needed to these amounts when using a highly water soluble drug. In this case these modifications are not known or

obvious to one skilled in the art. Rather reaching the ranges claimed in new claim 31 required extensive experimentation (as described in Applicant's specification). Moreover, if Heiligenstein teaches a composition comprising venlafaxine, as maintained by the Examiner, then Heiligenstein teaches only a composition comprising 8% w/w venlafaxine and 25.8% w/w hydrophobic polymer layer. One skilled in the art using 8% w/w venlafaxine and 25.8% w/w hydrophobic polymer layer as taught by Heiligenstein would not obtain a successful result. No direction is given in Heiligenstein as to how to modify these amounts in order to obtain a successful result. Thus, new claim 31 is not obvious from Heiligenstein, nor are claims 29 and 30. Therefore, these claims and all the claims dependent thereon define non-obvious subject matter over Heiligenstein. The Examiner finds this argument unpersuasive, because this is a 103 rejection, not a 102 rejection, wherein as discussed above, this is a simple routine optimization of adjusting the ingredients. The person of ordinary skill in the art obviously knows that adjustment is necessary since the therapeutic range of duloxetine is 1-30mg and venlafaxine is 10-150mg (see pg. 4, line 47-48) and to meet the bioequivalence requirement of the Food and Drug Administration.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618